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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,901	04/19/2004	Hovanes John Ter-Zakarian	12,616	2222

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EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,901	TER-ZAKARIAN, HOVANES JOHN	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on July 9, 2007 has been entered.

See rejections below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frenkel et al. (Increased urinary leukotriene E4 during febrile attacks in the hyperimmuno-globulinaemia D and periodic fever syndrome – previously presented) in view of Sims et al. (US Pat Applic. 2001/0053764– previously presented) and PDR (53rd edition 1999– previously presented).

Frenkel et al. teaches "leukotreine receptor antagonists might offer a new therapeutic approach for patients with the hyperimmunoglobulinaemia D and periodic fever syndrome."

Sims et al. teaches that periodic fever syndrome include familial Mediterranean fever (p. 8, paragraph [0054]).

The references do not specifically teach the leukotreine receptor antagonists in a dosage between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years, nor the leukotreine receptor antagonists consisting of Zafirlukast or Singulair.

However, the PDR (53rd edition 1999) teaches that singular tablets are orally active leukotriene receptor antagonist (p. 1886 Description). The recommended dosage amount for adolescents and adults 15 years of age and older is 10 mg tablets daily and for pediatric patients 6 to 14 years of age in one 5 mg. Chewable tablet daily (p. 1889 Dosage and administration).

Additionally, the PDR (53rd edition 1999) teaches that Zafirlukast is a selective peptide leukotriene receptor antagonist (see p. 3402 Description). The recommended oral dosage of Zafirlukast is 20 mg twice daily in adult and children 12 years and older.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to employ a leukotriene receptor antagonist of Frenkel et al. in the dosage amount between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years, and the leukotreine receptor antagonists consisting of Zafirlukast or Singulair. Further, it would have been obvious to lower the dosage of Zafirlukast in children because it is known that recommended children's intake of drugs are at lower dosages than adults. This is further distinguished by PDR's teachings that singular, a leukotriene

receptor antagonist, is given to adults and children at different concentrations. The motivation to use a leukotriene receptor antagonist of Frenkel et al. in the dosage amount between 5 and 15 milligrams, administered orally, on a daily basis, to humans between the age of 9 and 72 years is because the PDR teaches that (1) the said leukotriene receptor antagonist are therapeutically effective in the dosage range claimed, (2) administered orally, (3) on a daily basis, and (4) to patients in the claimed age range. Therefore, a skilled artisan would have reasonable expectation of successfully producing a therapeutically effective oral pharmaceutical formulation in the dosage range claimed.

Response to Arguments

Applicant's arguments filed on June 27, 2007 have been fully considered.

Applicant's amendments submitted June 27, 2007 is acknowledged wherein claims 1,3-7 are amended and claim 2 is canceled.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-7 over Frenkel et al. (Increased urinary leukotriene E4 during febrile attacks in the hyperimmuno-globulinaemia D and periodic fever syndrome) in view of Sims et al. (US Pat Applic. 2001/0053764) and PDR (53rd edition 1999) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments against the Frenkel teachings have been considered but are not found persuasive. There is reasonable suggestion by the prior art reference that a skilled artisan would have expected a leukotreine receptor

antagonist would have been useful in treating patients with familial Mediterranean fever. Furthermore, in response to applicant's argument that the reference "makes no mention of FMF and its treatment," Examiner draws Applicants attention to the Sims reference, where the relationship between periodic fever and FMF is clearly taught.

Applicant points to the paper "What We Treat" and argues that FMF is clearly distinguished from hyperimmunoglobulinaemia D and periodic fever syndrome. In fact, the reference clearly teaches that FMF is the most common periodic fever symdrome (please see heading Healing Familial Mediterranean fever of "What We Treat").

Examiner agrees that the Frenkel reference identifies HIDS as a type of periodic fever. However, the abstract clearly demonstrates that leukotreine receptor antagonists might offer a new therapeutic approach for a genus of periodic fever syndromes and hyperimmunoglobulinaemia D. Therefore, one of ordinary skill in the art would have reasonable expectation that any periodic fever syndrome would encompass the teachings.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Applicant argues there is no suggestion by Frenkel et al. to use a leukotreine receptor antagonists for oral administration. Examiner incorporated the PDR reference to show that leukotreine receptor antagonists are known for oral administration.

In response to the argument against the Sims reference, Examiner states the Sims et al. reference is solely used to show the relationship between periodic fever syndromes and Familial Mediterranean fever.

Applicant's arguments are not persuasive.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).